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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,981	10/31/2003	Sheryl E. Siegel	200.1162US	8850

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
07/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/698,981	SIEGEL, SHERYL E.
	Examiner	Art Unit
	MICAH-PAUL YOUNG	1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,6,74-80,82,84,86,88,90-95 and 97-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6,74-80,82,84,86,88,90-95 and 97-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 1/14/11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 6, 74-80, 82, 84, 86, 88, 90-95 and 97-108 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Masson et al (USPN 5,419,920 hereafter '920) and Cuca et al (USPN 5,494,681 hereafter '681).

The '920 patent discloses a method of imparting a scent or scent profile to an object and further detecting that scent at a later time (abstract). The scent is imparted at a level below that of the human olfactory sense, such that it is detectable by a non-human animal (col. 1, lin. 50-55). The scent is associated with the object or portion of the object and is used to authenticate the object in case of loss or theft. Further the authentication would allow for differentiation between authentic and counterfeit objects (col. 1, lin. 15-25). The scent is imparted to the object

during the manufacturing process (col. 4, lin. 23-31). The scent is absorbed into a substrate such as film, fiber or sponge, where the substrate is a polyolefin such as polyethylene (*Ibid.*).

What is lacking from the '920 reference is a disclosure of a specific dosage form and drug.

The combination of a scent to a dosage form comprising a drug is well known as seen in the '681 patent. The '681 patent discloses a tasteless drug dosage form comprising opioids such as codeine and morphine (col. 3, lin. 29-31). The dosage form can be a capsule (col. 6, lin. 55-65). The dosage form comprises essential oils and synthetic oils such as peppermint, spearmint, and fruit oils such as orange, lemon and grape (col. 7, lin. 1-15). It would have been obvious to track and identify the dosage form of the '681 patent by the method of the '920 patent in order to keep track of schedule 1 substances from a distance. It is further noted that the instant claims do not recite an active step of "authenticating" the dosage form, but only "allowing" for the dosage form to be authenticated. Clearly providing a dosage form with a scent, such as orange, etc. in the '681 patent would "allow" (render capable) the dosage form to be authenticated via smell, thus meeting the allowing step recited in the instant claims.

Regarding the differentiation between batches, it would be obvious to apply different flavors to different batches in order to tell them apart after manufacture. Varying the scent profile with different batches would allow the artisan of ordinary skill to tell the difference between codeine, morphine and other opioid analgesics.

With these things in mind it would have been obvious to combine the prior art in order to detect and track drug compositions from a distance. The '920 patent establishes the level of skill in the art regarding imparting a traceable scent to a polymeric film. These scented polymeric

forms can be found in drug dosage forms as seen in the '681 patent. It would have been obvious to tract the scented dosage forms of the '681 patent by the method of the '920 patent in order to prevent theft and reduce counterfeiting. Additionally, the '681 patent alone meets the limitations of "allowing for an authentication of the dosage form" by merely adding the scent, as explained above.

Response to Arguments

Applicant's arguments with respect to claims 3, 6, 74-80, 82, 84, 86, 88, 90-95 and 97-108 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618

/MICHAEL G. HARTLEY/
Supervisory Patent Examiner, Art Unit 1618